



Food and Drug Administration
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January 13, 2015

Smith & Nephew Incorporated
Mr. Vivek Mukhatyar
Regulatory Affairs Specialist II
150 Minuteman Drive
Andover, Massachusetts 01810

Re: K142948

Trade/Device Name: BIOSURE REGENESORB Interference Screw

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: MAI

Dated: December 17, 2014

Received: December 18, 2014

Dear Mr. Mukhatyar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142948

Device Name

The BIOSURE REGENESORB Interference Screw

Indications for Use (Describe)

The BIOSURE REGENESORB Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone-tendon-bone for the following indications:

Knee

ACL repairs

PCL repairs

Extra-capsular repairs

Medial collateral ligament

Lateral collateral ligament

Posterior oblique ligament

Patellar realignment and tendon repairs

Vastus medialis obliquus advancement

Iliotibial band tenodesis

Shoulder

Acromioclavicular separation repairs

Biceps tenodesis

Foot and Ankle

Medial or lateral instability repairs/reconstructions

Achilles tendon repairs/reconstructions

Metatarsal ligament/tendon repairs/reconstructions

Flexor hallucis longus (FHL)

Tendon transfers

Elbow, Wrist, and Hand

Biceps tendon reattachment

Ulnar or radial collateral ligament reconstructions

Lateral epicondylitis repair

Scapholunate ligament reconstruction

Tendon transfers

Carpometacarpal joint arthroplasty

NOTE: Only the 6mm, 7mm, 8mm, 9mm and 10mm diameter screws are intended to be used for bone-tendon-bone procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary**Date Prepared: December 16th, 2014**

SUBMITTER INFORMATION	CONTACT INFORMATION
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Vivek Mukhatyar Regulatory Affairs Specialist II Phone: (978)749-1043 Fax: (978)749-1443

DEVICE NAME (UNMODIFIED)	
Trade or proprietary name	BIOSURE REGENESORB interference screw
Common or usual name	Soft Tissue Fixation Device
Classification name	21 CFR §888.3030
Device Class	Class II
Product Code	MAI

LEGALLY MARKETING PREDICATE DEVICE

The Smith & Nephew BIOSURE REGENESORB interference screw is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

<i>Predicate Device</i>	<i>510(k) Number</i>	<i>Clearance Date</i>
BIOSURE HEALICOIL PK Interference Screw	K140879	07/21/2014
PLLA/HA Screw (BIOSURE HA)	K080358	12/14/2004
HEALICOIL Absorbable Suture Anchor (HEALICOIL REGENESORB)	K123393	4/11/2013

DEVICE DESCRIPTION

The Smith & Nephew's BIOSURE REGENESORB interference screw is an absorbable biocomposite interference screw with open lateral surface area for use in fixation of ligament, tendon, soft tissue, or bone-tendon-bone repairs in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The interference screw is provided sterile, for single use only.

INTENDED USE

The BIOSURE REGENESORB Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone-tendon-bone for the following indications:

Knee

ACL repairs
PCL repairs
Extra-capsular repairs
 Medial collateral ligament
 Lateral collateral ligament
 Posterior oblique ligament
Patellar realignment and tendon repairs
 Vastus medialis obliquus advancement
Iliotibial band tenodesis

Shoulder

Acromioclavicular separation repairs
Biceps tenodesis

Foot and Ankle

Medial or lateral instability
repairs/reconstructions
Achilles tendon repairs/reconstructions
Metatarsal ligament/tendon
repairs/reconstructions
Flexor hallucis longus (FHL)
Tendon transfers

Elbow, Wrist, and Hand

Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair
Scapholunate ligament reconstruction
Tendon transfers
Carpometacarpal joint arthroplasty

NOTE: Only the 6mm, 7mm, 8mm, 9mm and 10mm diameter screws are intended to be used for bone-tendon-bone procedures.

TECHNOLOGICAL CHARACTERISTICS

Smith & Nephew BIOSURE REGENESORB interference screw is substantially equivalent in intended use and fundamental scientific technology to the legally marketed predicate devices - Smith and Nephew BIOSURE HEALICOIL PK interference screw (K140879), HEALICOIL Absorbable Suture Anchor and BIOSURE HA (K080358) and raises no new issues of safety and efficacy. Smith & Nephew BIOSURE REGENESORB interference screw and the predicate Smith & Nephew HEALICOIL Absorbable Suture Anchor (K123393) are manufactured from the same composite material. Smith & Nephew BIOSURE HEALICOIL interference screw and the predicate BIOSURE HA (K080358) share the same thread structure and are both absorbable interference screws. BIOSURE REGENESORB has a similar open lattice design to the BIOSURE HEALICOIL PK interference screw (K140879).

SUMMARY OF PERFORMANCE DATA

Mechanical testing data for insertion and pull out (fixation) testing demonstrates the BIOSURE REGENESORB interference screw is substantially equivalent to the currently marketed predicate devices. The *in vitro* degradation of the device is substantially equivalent to the predicate BIOSURE HA (K080358).

SUBSTANTIAL EQUIVALENCE INFORMATION

The substantial equivalence of the BIOSURE REGENESORB interference screw is based on similarities in indications for use, design features, operational principles, material composition, and performance to the predicate devices listed above. Based on the similarities to the predicates, the BIOSURE REGENESORB interference screw is substantially equivalent to its predicates.